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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,345	03/12/2004	Christopher T. Ritchlin	21108.0031U2	6683

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Ballard Spahr LLP
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EXAMINER	
GABEL, GAILENE	
ART UNIT	PAPER NUMBER
1641	
MAIL DATE	DELIVERY MODE
12/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,345	RITCHLIN ET AL.	
	Examiner	Art Unit	
	GAILENE R. GABEL	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *RCE filed 10/27/09 & Amdt. filed 8/28/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-21,23,24,26-28,30-33,35,37,40-44 and 46-93* is/are pending in the application.

4a) Of the above claim(s) *7-11,17-20,32,41-44 and 46-93* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,13-16,21,23,24,26-28,30,31,33,35,37 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ ~~Notice of References Cited (PTO-892)~~
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ ~~Interview Summary (PTO-413)~~ Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-11,13-21,23,24,26-28,30-33,35,37,40-44 and 46-93.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 27, 2009 has been entered.

Amendment Entry

2. Applicant's amendment and response filed August 28, 2009 is acknowledged and has been entered. Claims 1, 15, and 33 have been amended. Claim 12 has been cancelled. Claims 7-11, 17-20, 32, 41-44, and 46-93 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Accordingly, claims 1-11, 13-21, 23, 24, 26-28, 30-33, 35, 37, 40-44, and 46-93 are pending. Claims 1-6, 13-16, 21, 23, 24, 26-28, 30, 31, 33, 35, 37, and 40 are under examination.

Withdrawn Objections / Rejections

3. All rejections or objections not reiterated herein, have been withdrawn.

4. The rejections of claim 12 are now moot in light of Applicant's cancellation of the claim.

5. The provisional rejection of claims 1-3, 13-16, 21-26, and 33-36 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3, 11-13, 15, 16, 21-26, 33-36 of copending Application No. 10/548,839 is now moot in light of Applicant's abandonment of the copending application.

6. In light of Applicant's amendment, the rejection of claims 1-6, 14, 21, 23, 24, 28, 30, 35, and 40 under 35 U.S.C. 102(a) as being anticipated by Hirayama et al. (Osteoclast formation and activity in the pathogenesis of osteoporosis in Rheumatoid Arthritis, Rheumatology 41: 1232-1239 (2002)), is hereby, withdrawn.

7. In light of Applicant's amendment, the rejection of claims 1-5, 12, 14, 21, 23, 24, 26-28, and 35 under 35 U.S.C. 102(a) as being anticipated by Jevon et al. (Osteoclast formation from circulating precursors in Osteoporosis, Scand J Rheumatol 32: 95-100 (January 1, 2003)), is hereby, withdrawn.

8. In light of Applicant's amendment, the rejection of claims 13, 15, 16, 31, 33, 37 under 35 U.S.C. 103(a) as being unpatentable over Hirayama et al. (Osteoclast formation and activity in the pathogenesis of osteoporosis in Rheumatoid Arthritis, Rheumatology 41: 1232-1239 (2002)) in view of Li et al. (Systemic TNFα Promotes Erosive Bone Resorption by Increasing the Number of CD11b+ Osteoclast Progenitors in the Periphery which are Dependent on RANK Signaling of Osteoclastogenesis, Journal of Bone and Mineral Research: JBMR Program and Abstracts (2002)), is hereby, withdrawn.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-6, 13-16, 21, 23, 24, 26-28, 30, 31, 35, 37, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in reciting, "an increase in the number of OCP in the subject relative to a healthy control subject indicates the presence of erosive arthritis" because the term "increase" is a subjective term that lacks a comparative basis for defining its metes and bounds. Additionally, the term "healthy" in terms of control subjects is a subjective term that lacks a comparative basis for defining its metes and bounds. Does Applicant intend the subjects as having no PsA and no erosive arthritis? See also claim 15.

Claim 26 is indefinite in reciting, "an increased number of osteoclasts in the culture from the subject relative to the number of osteoclasts in a culture of PBMC from a control subject without erosive arthritis indicates the subject has erosive arthritis" because the term "increased" is a subjective term that lacks a comparative basis for defining its metes and bounds. Additionally, does Applicant intend [healthy] control subjects without erosive arthritis to encompass those healthy control subjects having no PsA as well?

Claim 35 is vague and indefinite in being incomplete in reciting, "A method of determining whether a subject has erosive arthritis comprising ... probing for three or more surface markers of mononuclear OCP... selected from the group consisting of ..." because the claim omits essential structural and functional cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. In this case, claim 35 fails to clearly define how probing for three of more surface markers of mononuclear OCP provides indication of erosive arthritis. How does each one of the elected species, i.e. CD14, CD11b, CD51, and RANK, change independently and differentially (increase or decrease quantitatively) in expression so as to provide diagnostic indication of erosive arthritis?

Claim 37 is objected to for depending from a cancelled claim.

New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 15 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In this case, the specification does not appear to provide any literal support or written description supporting the recitation of "wherein greater than 2.5 times more nucleated cells in the sample from the subject than in the sample from the healthy control indicates erosive arthritis" and "wherein greater than 2.5 times more OCP in the PBMC of the subject than in a sample from a control subject without erosive arthritis indicates the presence of erosive arthritis in the subject." Applicant points to page 99, lines 1-6 and Figure 3, Figure 1, and Figure 26 of the specification for supposed support of the recited limitations. However, review of the disclosure in page 99, lines 1-6, reveals that the comparative basis of data sets is between psoriatic arthritis (PsA) patients with erosive arthritis and PsA patients without bone erosions; hence, the specification fails to provide literal or descriptive support for such recitations encompassing "[healthy] control subjects without erosive arthritis", since the median provided in page 99 encompasses "PsA subjects without erosive arthritis" and does not include any and all healthy control subjects such as those without PsA. See also Figure 1 wherein healthy control subjects having no PsA have about 0-10 OCPs per 10^6 PBMCs and are not representative part of the median value disclosed in the specification at page 99; thus, fails to provide literal or descriptive support for such recitation. Furthermore, none of the originally filed claims recited the limitation in question. Recitation of claim limitation lacking literal support in the specification or originally filed claims constitutes new matter.

Response to Arguments

11. Applicant's arguments with respect to claims 1-6, 13-16, 21, 23, 24, 26-28, 30, 31, 33, 35, 37, and 40 have been considered but are moot in light of Applicant's amendment and in view of the new grounds of rejection.

Applicant argues that "erosive arthritis" is a particular form of arthritis with a particular type of bone loss whereupon erosive arthritis patients display focal erosions affecting the immediate subchondral bone and bone at the margins.

Applicant's argument is persuasive because upon further search and examination, it is determined that the type of bone loss whereupon patients display focal erosions affecting the immediate subchondral bone and bone at the margins as disclosed by Applicant are specifically manifested in patients having inflammatory osteoarthritis or erosive osteoarthritis patients, and are not manifested in either one of rheumatoid arthritis patients and psoriatic arthritis patients.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAILENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, Thursday, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

December 28, 2009